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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|-----------------|--|----------------------|---------------------|------------------|--|
| 10/600,674 | 06/20/2003 | Robert G. Aslanian | AL01583K1 | 6070 | |
| 24265 | 7590 07/08/2004 | | EXAMINER | | |
| | -PLOUGH CORPOR | CHANG, CELIA C | | | |
| | PARTMENT (K-6-1, 1 PING HILL ROAD | (1990) | ART UNIT | PAPER NUMBER | |
| KENILWOR | KENILWORTH, NJ 07033-0530 | | | 1625 | |

DATE MAILED: 07/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | | | | |
|--|---|---|--|--|--|--|
| | 10/600,674 | ASLANIAN ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | Celia Chang | 1625 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | 36(a). In no event, however, may a reply be time within the statutory minimum of thirty (30) days will apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE | ely filed s will be considered timely. the mailing date of this communication. O (35 U.S.C. § 133). | | | | |
| Status | | | | | | |
| 1) Responsive to communication(s) filed on 20 Ju | <u>ıne 2003</u> . | | | | | |
| , | action is non-final. | | | | | |
| | | | | | | |
| Disposition of Claims | | | | | | |
| 4) Claim(s) 1-24 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) 1-24 are subject to restriction and/or election requirement. | | | | | | |
| Application Papers | | | | | | |
| 9)☐ The specification is objected to by the Examiner. | | | | | | |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| Attachment(s) | | | | | | |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) | 4) | | | | | |
| 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date | | atent Application (PTO-152) | | | | |

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2.

DETAILED ACTION

1. Claims 1-24 are in the case.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 15, drawn to M1 is N, M2 is CR3, n=2, p+r=3, R1 is 1, 2, 3-indolyl, bispiperidinyl indolyl compounds, classified in class 546, subclass 187. If this group is elected, claims 1-14, 16 will be prosecuted to the extend wherein M1 is N, M2 is CR3, n=2, p+r=3, R1 is 1, 2, 3-indolyl. Claim 17-19 can be prosecuted together with the elected compounds to the extend of the elected compounds upon election of a single disclosed disorder treatable by the elected compounds.
- II. Claims 1-14, 16, drawn to M1 is N, M2 is CR3, n=1, p+r=3, R1 is 1, 2, 3-indolyl, pyrrolidinylpiperidinyl indolyl compounds classified in class 546, subclass 201. If this group is elected, claims 1-14, 16 will be prosecuted to the extend wherein M1 is N, M2 is CR3, n=1, p+r=3, R1 is 1, 2, 3-indolyl. Claim 17-19 can be prosecuted together with the elected compounds to the extend of the elected compounds upon election of a single disclosed disorder treatable by the elected compounds.
- III. Claims 1-14, 16, drawn to M1 is N, M2 is CR3, n=3, p+r=3, R1 is 1, 2, 3-indolyl, azepidinyl piperidinyl indolyl compounds, classified in class 540, subclass 596. If this group is elected, claims 1-14, 16 will be prosecuted to the extend wherein M1 is N, M2 is CR3, n=3, p+r=3, R1 is 1, 2, 3-indolyl. Claim 17-19 can be prosecuted together with the elected compounds to the extend of the elected compounds upon election of a single disclosed disorder treatable by the elected compounds.
- IV. Claims 1-14, 16, drawn to remaining compounds, classified in class various, subclass various, depending on species election. If this group is elected, a further election of a single disclosed species is also required. Further restriction based

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on the elected species to the "core" structure i.e. the kind and size of the rings will be made.

V. Claims 20-24, drawn to multiple active ingredients composition and method of use, classified in class 514, subclass various, depending on species election. If this group is elected, a further election of a single disclosed species of compound and one additional active ingredient is also required. Further restriction may be required.

The inventions are distinct, each from the other because of the following reasons:

Compounds of groups I-IV differ in elements, bonding arrangement and chemical property. Compounds of groups I-IV lacks a common core since ring size, kind of ring and its linker are all variables. The members of the recited compounds are so disparate chemically as not to be members of a recognized chemical class of compounds. The combination is so complex that the identification of each class and subclass of compounds would be prohibitively many pages. Therefore, individual identification of core structure was delineated for three groups with the remaining structure in the fourth groups for a species election. Upon election of a species for the remaining compounds a generic concept surrounds that species will be created for search and examination purposes.

The multiple active ingredient composition and method of use is patentably independent and distinct from the compound per se inventions because multiple active ingredient composition and the method of using depends on the kind of ingredient in the combination and their individual quantities. The search and merit examination are unrelated to the compound per se inventions of groups I-IV.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Should applicant traverse on the ground that the groups and/or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the groups and/or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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In the instant case, then there would have been no patentability of all the claims since US 5,869,479 recited in the specification renders the combination composition and method obvious.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane, can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang July 1, 2004 Celia Chang Primary Examiner Art Unit 1625